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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/085,864	02/27/2002	Nicholas V. Perricone	NP-22 (acne)	3775	
24126 75	24126 7590 10/03/2003			EXAMINER	
ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET			OSTRUP, CLINTON T		
	RD, CT 06905-5619		ART UNIT	PAPER NUMBER	
		•	1614	_	
			DATE MAILED: 10/03/2003	i 4	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application N .	Applicant(s)		
		10/085,864	PERRICONE, NICHOLAS V.		
	Office Action Summary	Examiner	Art Unit		
		Clinton Ostrup	1614		
Period fo	The MAILING DATE of this communication app r Reply	ears on the cover sheet with the o	correspondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status					
1)⊠	Responsive to communication(s) filed on 18 A	august 2003 .			
2a)□		s action is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
	on of Claims				
4)⊠ Claim(s) <u>1-19</u> is/are pending in the application.					
_	a) Of the above claim(s) is/are withdraw	vn from consideration.			
	Claim(s) <u>16-19</u> is/are allowed.				
	Claim(s) <u>1-15</u> is/are rejected.				
	Claim(s) is/are objected to.				
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers					
_	•				
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
. • ,		·			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12)⊠ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. Certified copies of the priority documents have been received.					
:	2. Certified copies of the priority documents have been received in Application No.				
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) The translation of the foreign language provisional application has been received.					
15)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)					
1)  Notice 2)  Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u>	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)		

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### **DETAILED ACTION**

Claims 1-19 are pending in this application.

### **Priority**

Priority to Application Number 09/900,680, filed July 6, 2001 has been acknowledged.

#### Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to **patentability** as defined in 37 CFR 1.56. (Emphasis added).

#### Election/Restrictions

Applicant's election without traverse of Group I, claims 1-19, in Paper No. 9, filed May 8, 2003, and Applicant's election of dimethylaminoethanol in Paper No. 19, filed August 18, 2003, has been acknowledged. Applicant states that claims 4-6 and 17-19 are readable on this species, however, in order to expedite prosecution, the examiner has searched and examined claims 1-19 to the extent that they read upon the elected species.

# **Double Patenting**

Claims 1-6 and 13-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,319,942. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the instant claims are drawn to a method of treating acne by applying a composition comprising alkanolamine, tyrosine, and a sulfur ingredient to skin. The claims of 6,319,942 are drawn to a method for the treatment or inhibition of cutaneous scars, including acne scars (claim 18), by applying lipoic acid, tyrosine, and dimethylaminoethanol.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating acne scars as taught by 6,319,942, by treating acne generally, because of the reasonable expectation that a composition comprising lipoic acid, tyrosine, and dimethylaminoethanol which is useful in the treatment of acne scars would also be useful in the treatment of acne generally.

Claims 1-6 and 13-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,365,623. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of treating acne by applying a composition comprising alkanolamine, tyrosine, and a sulfur ingredient to skin. The claims of 6,365,623 are drawn to a method of reducing acniform scars by applying lipoic acid, tyrosine, and dimethylaminoethanol.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating acneiform scars as taught by 6,365,623, by treating acne generally, because of the reasonable expectation that a composition comprising lipoic acid, tyrosine, and dimethylaminoethanol which is useful for acneiform scars would also be useful in the treatment of acne generally.

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## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The term "preventing" is synonymous with the term "curing", and both circumscribe methods of treatment having absolute success. Since absolute success is not reasonably possible with most diseases, especially ones having etiologies as complex and multifactorial as acne, the specification is viewed as lacking an adequate written description of same (indeed, it could not provide one). However, the specification provides an adequate written description for a method of "treating" acne as claimed in claims 1-15.

### Allowable Subject Matter

Claims 16-19 are allowed.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup

Examiner

Art Unit 1614

Frederick Krass

Primary Examiner

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October 1, 2003